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SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 03 79 6822

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X Y	US 5 045 072 A (CASTILLO MIGUEL A [US] ET AL) 3 September 1991 (1991-09-03) * figure 1 * * column 3, lines 3-5,16,30-45 *	1,9 4-6,10, 11,14,16	INV. A61M1/00 A61M25/00 A61M25/01
Y	WO 99/17827 A (SCIMED LIFE SYSTEMS INC [US]) 15 April 1999 (1999-04-15) * page 4, lines 1-4,24-30 * * page 7, lines 4-6 *	4-6,10, 11,14,16	
A	US 5 300 048 A (DREWES JR DAVID A [US] ET AL) 5 April 1994 (1994-04-05) * the whole document * * figures 1,2 *	1-16	
A	US 5 814 016 A (VALLEY KIRSTEN L [US] ET AL) 29 September 1998 (1998-09-29) * abstract * * column 27, lines 23-31 *	1-16	TECHNICAL FIELDS SEARCHED (IPC)
A	EP 0 970 715 A (CORDIS CORP [US]) 12 January 2000 (2000-01-12) * abstract * * column 8 * * figure 1 *	1-16	A61M

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
Munich	19 December 2007	Türkavci, Levent

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 03 79 6822

This annex lists the patent family membersrelating to the patent documents cited in the above–mentioned European search report. The members are as contained in the European Patent Office EDP file on
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19-12-2007

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(74) Agents: CROMPTON, David, M. et al.; Crompton, Seager & Tufte, LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401-2246 (US).

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(54) Title: BRAIDED ANGIOGRAPHY CATHETER HAVING FULL LENGTH RADIOPACITY AND CONTROLLED FLEXIBILITY

(57) Abstract

A guiding catheter or angiographic catheter for use in cardiovascular interventions which incorporates a low-flexibility multi-layer proximal zone wherein a transition zone separates the proximal zone and a high flexibility distal zone. A mid-region zone transitions the high stiffness of the proximal zone to the higher flexibility of the distal zone to eliminate buckling and kinking. All zones of the catheter have a sufficiently large and substantially similar radiopacity, which allows the entirety of the catheter to be visible in a fluoroscope or other form of X-ray so that the positioning of the catheter can be precisely determined.

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BRAIDED ANGIOGRAPHY CATHETER HAVING FULL LENGTH RADIOPACITY AND CONTROLLED FLEXIBILITY

Technical Field

This invention relates to the field of intravascular medical devices, and more particularly, to the field of catheters such as angiographic and guide catheters used for the placement of medicines and medical devices within the body. Specifically, the invention is directed to an improved guide or diagnostic catheter having full length radiopacity incorporating a proximal zone having lower flexibility than a distal zone, where a transition zone provides varying flexibility between the proximal zone and the distal zone for improved catheter performance.

Background of the Invention

Angiographic and guide catheters are well known in the field of medicine for use in conjunction with other catheters for the treatment of cardiovascular disease through such procedures as percutaneous transluminal coronary angioplasty (PTCA) procedures. Guide catheters aid in treatment of arterial lesions by providing a conduit for positioning dilatation balloon systems across an arterial stenosis. The need for a greater variety of guide catheters to treat different types of circumstances has grown tremendously as the techniques for the use of such devices has grown.

During the treatment of cardiovascular disease, the catheter must be able to traverse tortuous pathways through blood vessels in a manner that minimizes trauma. In order for the physician to place the catheter at the correct location in the vessel, the physician must apply longitudinal and rotational forces. The catheter must be stiff enough to resist the formation of kinks, while at the same time, the catheter must possess flexibility to be responsive to maneuvering forces when guiding the catheter through the vascular system. The catheter must be rigid enough to push through the blood vessel, but yet flexible enough to navigate the bends in the blood vessel. The guide or angiographic catheter must exhibit good torque control such that manipulation of a proximal portion of the catheter is responsively translated to the tip or distal end of the catheter to curve and guide the catheter through the tortuous pathways. Thus, the catheter must have torsional rigidity to transmit the applied torque. To accomplish this balance between

longitudinal rigidity, torsional rigidity and flexibility, often times a support member is added to the shaft. This support member is often comprised of a metal braid or a coil embedded in the shaft.

In many applications, the catheter is guided through the aorta over the aortic arch and down to the ostium of the vessel which is to be treated. It is preferable to have a soft tip or flexible section engage the ostium. Therefore, it is advantageous to have the proximal section more rigid to transmit the forces applied, but have the distal end more flexible to allow for better placement of the catheter. Having the distal section more flexible also creates a less traumatic section to contact the blood vessel. The distal end of the catheter is rotated, through the transmission of torque from the proximal end, until the tip of the catheter is in the desired position. With the variation of different bend shapes available on the distal ends of these devices and with variations in patient anatomy, each device may need to be torqued more or less in order to correctly place it.

In order to meet these performance requirements, catheters are often manufactured using polymers in conjunction with the above-mentioned support member using a metal braid or coil, wherein the support member is incorporated into the tube of the guide catheter. Catheters can be formed of three layers. An inner tubular member is used which defines an inner lumen which may be formed of a material that decreases the coefficient of friction such as that encountered between a balloon catheter and the inner lumen of the catheter. The support member conforms to the outside of the inner layer and is often comprised of a metal braid or coil. The third outer tube is commonly formed from a polymer and overlays the support member.

In order to meet the above requirements of rigidity and flexibility, a catheter is desired which has regions of varying stiffness which may be readily changed during manufacturing to meet the need for the greater variety of devices necessary to treat different types of circumstances.

An example of one approach is described in U.S. Patent No. 5,533,985, issued July 9, 1996 to James C. Wang, for Tubing, which is incorporated herein by reference. Wang discloses differential stiffness tubing for medical products, including catheters, wherein the tubing has a stiff section and a flexible section joined by a relatively short

transition section in which the materials of the stiff and flexible sections are joined into each other in a smooth gradual manner to produce an inseparable bond between the materials without abrupt joints. This tubing is manufactured using an extrusion process and may be limited in its ability to manufacture catheters having the desired number of regions of varying stiffness and the ability to easily accommodate product design changes during manufacture.

Catheters may be manufactured using this approach, but its practical application may be limited to joining two materials to form two zones of flexibility with a transition therebetween. Thus, with this approach, additional manufacturing steps are necessary to provide for additional regions. These regions of varying stiffness are necessary to provide rigidity to push the catheter through the blood vessel, flexibility to navigate the bends in the blood vessel, and torsional stiffness to correctly place the catheter by maintaining torque control without excessive energy storage which can cause undesirable movement of the catheter end.

It is advantageous that the catheter be visible in a fluoroscope or other form of x-ray, so that the catheter can be positioned with precision. In the prior art, this has been accomplished by applying a metal ring to the catheter adjacent the distal end. It is generally undesirable to place the metal ring exactly on the distal tip of the catheter, since the distal tip needs to be very soft and pliable. Therefore, the metal ring does not completely resolve the problem of precisely locating the distal tip of the catheter within the body by means of a fluoroscope during a medical procedure, since the metal ring is and must be spaced from the distal tip. In other prior art, the distal tip has been manufactured to be substantially more radiopaque than portions of the catheter proximal to the tip.

Summary of the Invention

The present invention overcomes many of the disadvantages found in the prior art by providing a guiding catheter for use in coronary angioplasty and other cardiovascular interventions which incorporates a lower flexibility proximal shaft portion, coupled to a higher flexibility distal tip portion. Within the distal tip, there are three distinct zones of flexibility. A tip transition portion separates a proximal tip portion

from a distal tip portion. The transition portion gradually transitions the lower flexibility of the proximal portion to a higher flexibility of the distal portion via a gradual transition in materials from a higher durometer polymer to a lower durometer polymer to eliminate buckling and kinking. Therefore, when including the flexibility of the proximal shaft portion, the catheter of the present invention includes four distinct zones of flexibility.

The catheter also possesses a high level of radiopacity, said level being substantially similar throughout all portions of the device. It is particularly desirable for all portions of the device to be visible in a fluoroscope or other form of x-ray so that the positioning of the catheter can be precisely determined.

In a preferred embodiment of the present invention, a guide or angiographic catheter is provided comprising a linear shaft and a lumen extending longitudinally through the center of the linear shaft. The linear shaft is comprised of a proximal shaft portion of high radiopacity at the proximal end of the linear shaft, and a distal tip of high radiopacity which extends distally from the distal end of the proximal shaft portion to the distal end of the linear shaft. The distal tip is attached to the distal end of the proximal shaft portion by heat bonding. The radiopacity of all portions of the linear shaft is substantially similar.

The proximal shaft portion further comprises an inner tubular member defining the diameter of the center lumen, an intermediate tubular member overlying and conforming to the inner tubular member, a woven braid member overlying and conforming to the intermediate tubular member, an outer tubular member substantially overlying and conforming to the woven braid member and an outer sleeve tubular member substantially overlying and conforming to the outer tubular member.

The distal tip further comprises a proximal portion having a first material of a first stiffness, a transition portion having a second material with a continuous differential second stiffness, and a distal portion having a third material of a third stiffness. The first stiffness of the first material will be larger than the third stiffness of the third material. The second stiffness of the second material is defined by a gradual transition from the stiffness of the first material of the proximal portion of the distal tip to the stiffness of the third material of the distal portion of the distal tip.

Brief Description of the Drawings

Other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, in which like reference numerals designate like parts throughout the figures thereof and wherein:

Fig. 1 is a plan view with the manifold cross sectioned of a catheter showing a preferred embodiment of the present invention;

Fig. 2 is a cross section view of Fig. 1 taken along line 2-2;

Fig. 3 is a plan view of the distal tip area of the catheter of Fig. 1, illustrating the shaft/tip heat bonding site and the portions of the distal tip including a transition zone of varying stiffness.

Detailed Description of the Preferred Embodiments

Referring now to the drawings, wherein like reference numerals refer to like elements throughout the several views, Fig. 1 is a plan view of a catheter with the manifold shown in cross section showing a preferred embodiment of the present invention. Figure 1 shows a catheter 10 which comprises a hub 46, and a linear shaft 11 having a proximal end 12 and a distal end 14. A central lumen 16 extends longitudinally through the linear shaft from the proximal end 12 to the distal end 14. The linear shaft 11 comprises a proximal shaft 17 and a distal tip 20. The proximal shaft 17 has a proximal end 18 and a distal end 19. The distal tip 20 is attached to the distal end 19 of the proximal shaft 17 at the shaft/tip heat bonding site 48.

Referring now to Fig. 2, the proximal shaft portion 17 includes an inner tubular member 22 formed from polyurethane which extends from the proximal end 18 to the distal end 19 of the proximal shaft 17. The inner tubular member 22 defines the inner diameter 21 of the central lumen 16. An intermediate tubular member of polyether block amide copolymer (PEBA) 24, commercially available under the trademark PEBAX, is extruded over the entire length of the inner tubular member 22. The intermediate tubular member of PEBAX 24, has a durometer of 67D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

A woven braid member 26 is provided over the entire length of the intermediate tubular member 24. In one embodiment, the intermediate tubular member 24 and woven braid member 26 are passed through a heated dye so that the woven braid member 26 is slightly embedded in the outer surface of the intermediate tubular member 24. In a second embodiment, the intermediate tubular member 24 is substantially cooled before the woven braid member 24 is provided so that the woven braid member 26 is not embedded in the outer surface of the intermediate tubular member 24. The woven braid member 26 is preferably braided from strands of round 0.0020" annealed 304 stainless steel, and has a constant braid density of 40 pic/in over the length of the proximal shaft portion 17.

An outer tubular member 28 is extruded over the entire length of the woven braid member 26. The outer tubular member 28 is preferably manufactured from PEBAX and has a durometer of 67 D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer, and is not translucent. An outer sleeve tubular member of PEBAX 30 is extruded over the entire length of the outer tubular member of PEBAX 28. The outer sleeve tubular member of PEBAX has a durometer of 70 D, and is 30% loaded with a bismuth subcarbonate filler and a colorant (phthalocyanine blue and violet 23).

Referring now to Fig. 3, the distal tip 20 is attached to the distal end 19 of the proximal shaft portion 17 by a heat bonding process. The distal tip 20 has a lumen 34 extending therethrough which defines the central lumen 16 in the distal portion 15. The inner diameter of the tip lumen 36 defined by the distal tip 20 is substantially equal to the inner diameter of the lumen 21 defined by the inner layer of polyurethane 22 of the proximal shaft portion 17. The very distal end of the tip 53 is tapered and the inner diameter within the very distal end of the tip 53 is smaller to fit tightly over a guide wire.

The distal tip 20 is formed from PEBAX using an Interrupted Layer Coextrustion (ILC) process, which in preferred embodiments results in a proximal portion 38, a transition portion 40, a distal portion 42, and a distal end of distal tip 51. The proximal portion 38, transition portion 40, and distal portion 42 preferably have linear dimensions of about 1.25", 1.5" and 1.25", respectively, resulting in a total linear dimension of about 4".

The proximal portion 38 of the distal tip 20 has a durometer of 70 D, and is 55% loaded with a Tungsten filler and a 1% UV stabilizer. The distal portion 42 has a durometer of 47 D, and is also 55% loaded with a Tungsten filler and a 1% UV stabilizer. The transition portion 40 has a durometer ranging from 70 D at the proximal end 43 to 47 D at the distal end 44, as provided by the ILC process. Experiments show that the proximal shaft portion 17 has substantially the same radiopacity as the distal tip 20.

Referring back to Fig. 1, the proximal end 18 of the proximal shaft portion 17 extends into a hub 46 molded directly over the proximal shaft portion 17. A 63 D white PEBAX strain relief is insert molded to the hub, and the proximal shaft portion 17 extends into the hub 46 through the PEBAX strain relief 50.

Having thus described the preferred embodiments of the present invention, those of skill in the art will readily appreciate that yet other embodiments may be made and used within the scope of the claims hereto attached.

What is claimed is:

1. A tubular assembly for an intravascular catheter comprising:

a linear shaft having a proximal end, a distal end, and a lumen extending longitudinally therethrough;

a proximal shaft portion of high radiopacity included within said linear shaft, said proximal shaft portion extending distally a predefined distance from the proximal end of said linear shaft, wherein said proximal shaft portion has a proximal and distal end;

an inner tubular member contained within said proximal shaft portion;

an intermediate tubular member contained within said proximal shaft portion overlying said inner tubular member and conforming thereto;

a woven braid member contained within said proximal shaft portion overlying said intermediate tubular member and conforming thereto;

an outer tubular member contained within said proximal shaft portion substantially overlying said woven braid member said outer tubular member having a radiopaque agent dispersed therein; and

an outer sleeve overlying at least a portion of said outer tubular member.

2. The tubular assembly of claim 1 wherein the inner tubular member is formed from polyurethane.

3. The tubular assembly of claim 1 wherein the intermediate tubular member is formed of polyether block amide, having a durometer of 67 D, loaded with a Tungsten filler and/or UV stabilizer.

4. The tubular assembly of claim 1 wherein the woven braid member is braided from strands of stainless steel.

5. The tubular assembly of claim 1 wherein said woven braid is embedded in outer surface of said intermediate tubular member.

6. The tubular assembly of claim 1 wherein said intermediate tubular member is substantially cooled before said woven braid member is provided so that said woven braid is not embedded in outer surface of said intermediate tubular member.

7. The tubular assembly of claim 1 wherein said outer tubular member is formed of polyether block amide having a durometer of 67 D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

8. The tubular assembly of claim 1 wherein said outer sleeve tubular member substantially overlies all of said outer tubular member and conforming thereto.

9. The tubular assembly of claim 1 wherein said outer sleeve tubular member is formed from polyether block amide having a durometer of 70D, and is 30% loaded with a bismuth subcarbonate filler and 1% colorant (phthalocyanine blue, violet 23).

10. A tubular assembly for an intravascular catheter comprising:

a linear shaft having a proximal end, a distal end, and a lumen extending longitudinally therethrough;

a proximal shaft portion of high radiopacity included within said linear shaft, said proximal shaft portion extending distally a predefined distance from the proximal end of said linear shaft, wherein said proximal shaft portion has a proximal end and a distal end; and

a distal tip, said distal tip having a lumen therethrough, said distal tip included within said linear shaft portion extending distally from the distal end of said proximal shaft portion to the distal end of said linear shaft so that said lumen of said proximal shaft portion and said lumen of said distal tip form a continuous lumen extending from said proximal end of said proximal shaft portion through a distal end of said distal tip, said distal tip further comprising a proximal portion having a first material of a first stiffness, a transition portion having a second material with a continuous differential second

stiffness, and a distal portion having a third material of a third stiffness, wherein said transition portion is defined by a gradual transition from said first material of said distal tip proximal portion to said third material of said distal tip distal portion.

11. The tubular assembly of claim 10 further comprising:

an inner tubular member contained within said proximal shaft portion;

an intermediate tubular member contained within said proximal shaft portion overlying said inner tubular member and conforming thereto; and

a woven braid member contained within said proximal shaft portion overlying said intermediate tubular member and conforming thereto.

12. The tubular member of claim 10 wherein the distal tip is heat bonded to said distal end of said proximal shaft portion.

13. The tubular member of claim 10 wherein said distal tip is formed from polyether block amide.

14. The tubular member of claim 10 wherein said proximal portion, said transition portion, and said distal portion of said distal tip have linear dimensions of about 1.25", 1.5" and 1.25", respectively.

15. The tubular member of claim 10 wherein the first stiffness is greater than the third stiffness.

16. The tubular member of claim 10 wherein the second continuous differential stiffness of the second material of the distal tip transition portion is controlled by controlling the length of the gradual transition from the first material of the distal tip proximal portion to the third material of the distal tip distal portion.

17. The tubular member of claim 10 wherein substantially all portions of said proximal shaft and said distal tip have substantially similar radiopacity.

18. The tubular assembly of claim 11 wherein the inner tubular member is formed from polyurethane.

19. The tubular assembly of claim 11 wherein the intermediate tubular member is formed of polyether block amide, having a durometer of 67 D, loaded with a Tungsten filler and/or UV stabilizer.

20. The tubular assembly of claim 11 wherein the woven braid member is braided from strands of stainless steel.

21. The tubular assembly of claim 11 wherein said woven braid is embedded in outer surface of said intermediate tubular member.

22. The tubular assembly of claim 11 wherein said intermediate tubular member is substantially cooled before said woven braid member is provided so that said woven braid is not embedded in outer surface of said intermediate tubular member.

23. The tubular assembly of claim 11 further comprising:

an outer tubular member contained within said proximal shaft portion substantially overlying said woven braid member and conforming thereto.

24. The tubular assembly of claim 23 wherein said outer tubular member is formed of polyether block amide having a durometer of 67 D, is 80% loaded with a Tungsten filler and a 1% UV stabilizer.

25. The tubular assembly of claim 24 further comprising:

an outer sleeve tubular member contained within said proximal shaft portion substantially overlying said outer tubular member and conforming thereto.

26. The tubular assembly of claim 25 wherein said outer sleeve tubular member is formed from polyether block amide having a durometer of 70D, and is 30% loaded with a bismuth subcarbonate filler and 1% colorant (phthalocyanine blue, violet 23).

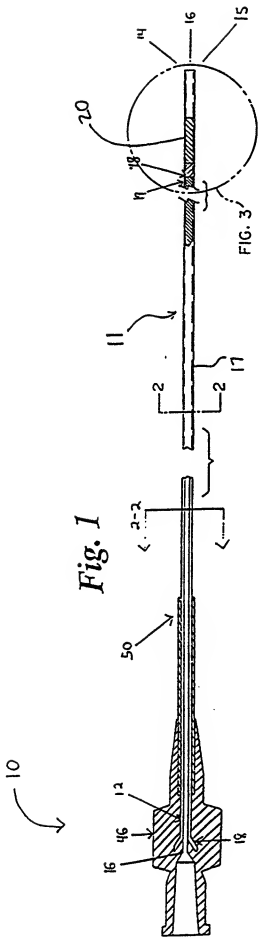

Fig. 1

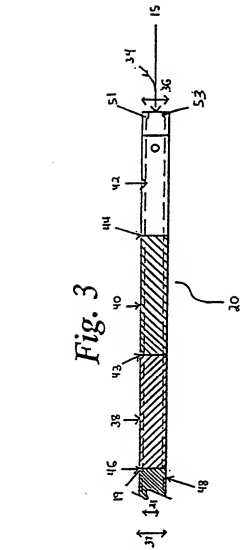

Fig. 3

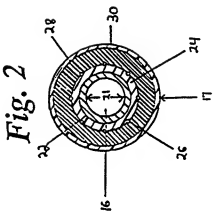

Fig. 2

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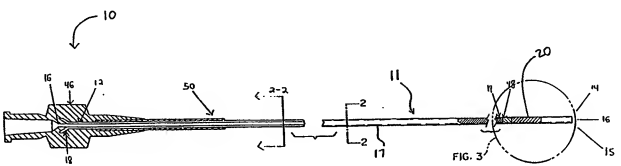

FIG. 3

(57) Abstract

A guiding catheter or angiographic catheter for use in cardiovascular interventions which incorporates a low-flexibility multi-layer proximal zone wherein a transition zone separates the proximal zone and a high flexibility distal zone. A mid-region zone transitions the high stiffness of the proximal zone to the higher flexibility of the distal zone to eliminate buckling and kinking. All zones of the catheter have a sufficiently large and substantially similar radiopacity, which allows the entirety of the catheter to be visible in a fluoroscope or other form of X-ray so that the positioning of the catheter can be precisely determined.

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CN	China	KR	Republic of Korea	PT	Portugal		
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CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/20800

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 33763 A (TARGET THERAPEUTICS) 31 October 1996 see page 25, line 23 - page 26, line 4; claims 16,27; figure 10 ---	1,2,4,6, 8
A	US 4 898 591 A (JANG) 6 February 1990 see column 5, line 7 - column 6, line 14; figures 1-3 ---	1-9
A	WO 96 38194 A (SCIMED LIFE SYSTEMS) 5 December 1996 see page 19, line 18 - page 21, line 29; figure 10 ---	1-9
A	US 5 403 292 A (JU) 4 April 1995 see the whole document ---	1,3-9

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 February 1999	19 05 1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	KOUSOURETAS, I

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 614 136 A (PEPIN) 25 March 1997 see column 8, line 17 - column 9, line 41; figure 8 ---	1,6,9
A	US 4 676 229 A (KRASNICKI) 30 June 1987 see column 4, line 49 - column 5, line 35; figure 3 -----	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/20800

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-9

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-9

A tubular assembly for an intravascular catheter comprising a linear shaft, a proximal shaft portion of high radiopacity, and contained within said proximal shaft portion an inner tubular member, an intermediate tubular member, a woven braid member, an outer tubular member and an outer sleeve overlying at least a portion of said outer tubular member.

2. Claims: 10-26

A tubular assembly for an intravascular catheter comprising a linear shaft, a proximal shaft portion of high radiopacity and a distal tip, said distal tip further comprising a proximal portion having a material of a first stiffess, a transition portion having a second material of a continuous differential second stiffness and a distal portion having a third material of a third stiffness, wherein said transition portion is defined by a gradual transition from said first material of said distal tip proximal portion to said third material of said distal tip distal portion.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/20800

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9633763 A	31-10-1996	US 5702373 A	30-12-1997
		AU 693357 B	25-06-1998
		AU 5578596 A	18-11-1996
		AU 6803098 A	01-10-1998
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(19) Europäisches Patentamt
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Office européen des brevets

(11) EP 0 970 715 A2

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AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

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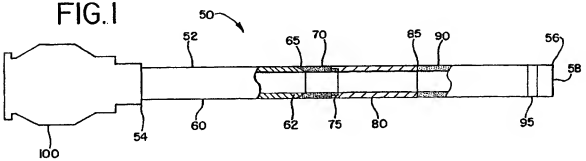
(54) Flow directed catheter having radiopaque strain relief segment

(57) A flow directed catheter for use in medical diagnostic or therapeutic procedures having a strain relief segment between the relatively stiff proximal section of the catheter and the floppy distal tip portion in which the strain relief segment is formed of a polymeric material containing a radiopaque agent.

FIG. 1



EP 0 970 715 A2

Description

Field of the Invention

[0001] A flow directed catheter for use in medical diagnostic or therapeutic procedures having a strain relief segment between the relatively stiff proximal section of the catheter and the floppy distal tip portion in which the strain relief segment is formed of a polymeric material containing a radiopaque agent.

Background Art

[0002] In order to diagnose the extent of coronary artery disease angiography procedures are used to view the blood flow through selected blood vessels. In carrying out this procedure diagnostic catheters are introduced into the blood vessels of a patient and are advanced over a guidewire through the vascular system of the patient until the distal end of the catheter is steered into the particular blood vessel to be examined.

[0003] In view of the fact that the human vasculature is quite tortuous it is essential that a diagnostic catheter be capable of being steered by torquing the proximal hub of the catheter in order to direct the catheter through the vascular system. With extremely small vessels it is often not possible to provide a catheter with sufficient flexibility for passage through the tortuous vasculature while still providing sufficient rigidity to steer, or torque, the distal end of the catheter to a desired site. Accordingly, in certain instances it is desirable to provide a catheter in which the proximal end of the catheter is relatively stiff and the distal end of the catheter is very flexible, or floppy, in order that the distal tip of the catheter may be steered, or directed, through the vasculature by means of the flow of blood through the vessel. Such catheters are generally referred to as flow directed catheters.

[0004] Such flow directed catheters generally comprise a connector hub, a relatively long and stiff proximal section for pushing the catheter into the vasculature system, and a shorter and very floppy distal tip section. The floppy distal tip section is of a very low durometer in order that the tip section may be guided, or directed, by the flow of blood through the blood vessel.

[0005] Medical catheters have for many years included a relatively short distal tip which is formed of a polymeric material containing a radiopaque agent in order that the distal tip of the catheter may be readily viewed under X-ray radiation as the catheter is passed through the blood vessels of a human body. With a radiopaque distal tip it is possible for the physician to observe the exact location of the distal tip portion of the catheter relative to its position within the human body.

[0006] Examples of prior art patents which disclose medical catheters having distal tips containing a radiopaque agent are United States Patent No. 5,045,072 entitled "Catheter Having Highly Radiopaque, Flexible Tip" to Castillo et al. and United States Patent No. 5,171,232 to entitled "Catheter Having Highly Radiopaque, Flexible Tip" Castillo et al., both of which are assigned to the assignee of the present application and are incorporated herein by reference

[0007] One problem with currently available flow directed catheters is that with these devices the physician is unable to determine the exact position of the transition area between the relatively stiff proximal portion of the catheter and the floppy distal portion of the catheter. With the inability to determine the location of this transition area it is very difficult to determine which portion of the catheter may be steered by torquing on the hub of the catheter and which portion of the catheter may not be so steered but may simply be permitted to be directed by the flow of blood through the blood vessel. In addition, it is difficult for the doctor to prevent kinking of the relatively soft floppy portion of the catheter as this portion of the catheter passes through the blood vessel if the doctor is unable to discern whether a particular portion of the catheter is formed of a relatively stiff material or a very floppy material.

Summary of the Invention

[0008] The present invention relates to a flow directed catheter intended for the insertion into the blood vessels of a patient which may be guided through the vasculature of the patient by a force exerted on the floppy distal portion of the catheter by the flow of blood through the vasculature. The catheter includes a strain relief section which is positioned between a relatively rigid proximal portion of the catheter and a floppy distal portion of the catheter and in which the strain relief section is formed of a polymeric material containing a radiopaque agent with this device, the physician may readily determine the exact position of the strain relief portion of the catheter or the position of the transition region between the relatively stiff portion of the catheter and the very floppy distal portion of the catheter.

[0009] Flow directed catheters constructed in accordance with the present invention include a proximal connector hub, a relatively stiff proximal tubular section bonded to the hub, a highly flexible distal tubular section, and a relatively short tubular strain relief section interposed between the proximal tubular section and the distal top section. The tubular strain relief section is more flexible than the proximate tubular section and less flexible than the distal tubular section and is formed of a polymeric material containing a radiopaque agent. With this device, a physician is able to precisely locate the position of the strain relief section of the catheter. The highly flexible tubular section is very floppy in nature and its position is controlled by the flow of blood through the blood vessel to thereby permit the physician to precisely position the distal tip of the catheter at a desired site.

[0010] In accordance with another aspect of the present invention, the tubular strain relief section is formed of a polymeric material containing from about 40

to 75 weight percent of radiopaque agent, such as barium sulfate, bismuth subcarbonate or bismuth trioxide.

[0011] In accordance with still another aspect of the present invention, the tubular strain relief section is thermally fused to the distal end of the proximal tubular section and the distal tubular section is thermally fused to the distal end of the strain relief section. In addition, the tubular strain relief section is preferably free of any metallic radiopaque member, such as a metal ring, which is positioned on or adjacent to the strain relief section.

[0012] In accordance with another aspect of the present invention, the highly flexible distal section, or floppy distal tip, is more than twenty times the length of the strain of the relief section and the relatively stiff proximal section of the catheter is more than ten times the length of the floppy distal section. In addition, the proximal tubular section preferably has a durometer of between 60D and 90D, the strain relief section has a durometer of between 25D and 50D and the distal tubular section has a durometer between 50A and 90A.

[0013] In accordance with still another aspect of the present invention, the distal floppy section has a length of between 10 and 50 centimeters and may be comprised of an inner distal section and an outer distal section in which the inner distal section is more flexible than the strain relief section of the catheter and the outer distal section is more flexible than the inner distal section.

[0014] From the above it may be appreciated that one object of the invention is a flow directed catheter with a floppy distal tip which may be directed through the vasculature by the flow of blood and in which a radiopaque strain relief section is positioned between the floppy distal tip and a relatively stiff proximal section to thereby provide the physician with an exact location of the transition area between the relatively stiff proximal section and the floppy distal tip of the catheter. This and other objects, advantages and features of the invention will become better understood from a detailed description of the invention which is described in conjunction with the accompanying drawings:

BRIEF DESCRIPTION OF THE DRAWINGS

[0015]

Figure 1 is a partially crossed-sectional view of the flow directed catheter of the present invention which illustrates the various section of the catheter;

Figure 2 is a partially crossed-sectional view of a flushable stilt for use with the flow directed catheter of Figure 1;

Figure 3 is an elevational view of the flow directed catheter of Figure 1 in conjunction with the flushable stylet of Figure 2; and,

Figure 4 is diagrammatic view showing the flow directed catheter of the present invention inserted in the tortuous vasculature of a human body.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

[0016] Figure 1 illustrates the assembled flow directed catheter 50 having a main tubular body 52 with a proximal end 54 and a distal end 56 and an inner lumen 58 extending there through. The main tubular body 52 is constructed from four segments; a relatively stiff proximal shaft segment 60, a radiopaque strain relief segment 70, a proximal floppy segment 80 and a soft distal floppy segment 90.

[0017] The relatively stiff proximal shaft segment 60 of main tubular body 52 is preferably made from a high durometer polymeric material or a polymer coated metallic hypotube. Suitable polymers for the proximal shaft segment 60 include biologically compatible polymers such as nylon, polyethylene, polyester, polyurethane, silicone and the like. The durometer of the proximal shaft segment 60 is between 60D and 90D and is preferably 75D. The proximal shaft segment 60 provides proximal support for flow directed catheter 50, enabling pushability without the need of a guidewire. The proximal shaft segment 60 comprises a proximal end 54 to which a hub coupling 100 is attached and a slight distal taper 62 to which the radiopaque strain relief segment 70 is attached. The length of proximal shaft segment 60 is between 100 cm and 145 cm preferably between 125 cm and 130 cm. The preferable inner diameter and outer diameter of proximal shaft segment 60 are about 0.55 mm and 0.94 mm respectively. The length of the slight distal taper 62 is between 0.1 mm and 3 mm more preferably between 1.5 mm and 2.5 mm.

[0018] The proximal shaft segment 60 is attached to the radiopaque strain relief segment 70 at the slight distal taper 62 by a thermal fuse joint 65. The thermal fuse joint 65 is created by placing the slight distal taper 62 of proximal shaft segment 60, while on a mandrel, inside of the radiopaque strain relief segment 70 and heating the assembly. Depending upon the materials used for the proximal shaft segment 60 and the radiopaque strain relief segment 70 the fusing temperature ranges from 300°F to 550°F. Preferably the fuse temperature is between 350°F and 450°F.

[0019] The radiopaque strain relief segment 70 provides the physician with a visible marker under fluoroscopy indicating the location of the relatively stiff proximal shaft segment 60 in relation to the guiding catheter tip. The radiopaque strain relief segment 70 also prevents kinking that occurs when a rigid tube is connected to a very flexible tube. The radiopaque strain relief segment 70 is more flexible than the proximal shaft segment 60 and made from a polymer tube that has been made radiopaque by incorporating radiopaque fillers during the forming process. The strain relief segment 60 is of a durometer of between about 25D and 50D and is preferably about 40D. Suitable fillers include powders made from metals such as tungsten and tantalum as well as compounds containing barium and bismuth such as bar-

ium sulfate, bismuth subcarbonate and bismuth trioxide. Preferably the strain relief segment 60 is formed of a polymeric material containing between 40 and 75 weight percent of the radiopaque agent. Since the incorporation of fillers generally increase the stiffness of a polymer the length of the radiopaque strain relief segment 70 must be fairly small, between 0.4 cm and 0.6 cm preferably about 0.5cm.

[0020] The radiopaque strain relief segment 70 is attached to a proximal floppy segment 80 by a thermal fuse joint 75. The proximal floppy segment 80 is more flexible, i.e. lower durometer than the radiopaque strain relief segment 70 and proximal shaft segment 60. The inner diameter of the radiopaque strain relief segment 70 and the proximal floppy segment 80 is between 0.25 mm and 0.55 mm preferably about 0.42 mm, while the outer diameter is between 0.60 mm and 0.94 mm preferably about 0.79 mm. The length of the proximal floppy segment 80 is between 10 cm and 20 cm preferably about 15 cm.

[0021] The proximal floppy segment 80 is attached to the distal floppy segment 90 by a thermal fuse joint 85. The distal floppy segment 90 is constructed from a low durometer polymer and is more flexible than the proximal floppy segmentile the outer diameter is between 0.25 mm and 0.76 mm preferably 0.61 mm. The length of the distal floppy segment is between 10 cm and 30 cm preferably about 20 cm. To make the distal tip of flow directed catheter 50 visible under fluoroscopy a radiopaque marker 95 is attached to distal floppy segment 90. To facilitate access to some vessels in tortuous anatomy the distal tip of the distal floppy segment 90 may be preshaped. The proximal floppy segment 80 is of a durorter between about 50A and 90A and preferably between about 70A and 80A. The distal floppy segment 90 is of a durometer of between about 50A and 90A and is preferably between about 65A and 75A.

[0022] To reduce damage while using, the flow directed catheter 50 is coated with a lubricious polymer. This coating may be hydrophobic or hydrophilic in nature, preferably hydrophilic, and applied to the interior and exterior of flow directed catheter 50. Hydrophilic coatings are widely known in the industry and may be applied using a dip coating process and subsequently dried, covalently bonded and crosslinked using a single thermal drying cycle. Preferably this drying temperature would be below the softening point of the polymers being coated about 50°C to 60°C. To facilitate the introduction of flow directed catheter 50 into the guiding catheter a stylet is inserted to provide support.

[0023] Figure. 2 illustrates a flushable stylet 250 for use with flow directed catheter 50. The flushable stylet 250 allows the hydrophilic coating on the interior of flow directed catheter 50 to be flushed and hydrated without removing the stylet. This procedure prevents damage to the interior coating of the flow directed catheter 50. Flushable stylet 250 consists of a hollow tube body 252, with a proximal end 254 to which a luer hub 290 is attached and having a distal end 256. The proximal end 254 of the tube body 252 is attached to luer hub 290 by using an adhesive or thermal fuse with the lumen of luer hub 290 remaining open. The tube body 252 may be coated with a hydrophobic or hydrophilic lubricious polymer, preferably hydrophobic. To facilitate introduction of the flushable stylet 250 into flow directed catheter 50, the tube body 252 may also be tapered.

[0024] Figure 3 illustrates the catheter sytlet assembly 300. The flushable stylet 250 is placed inside of flow directed catheter 50 coaxially. Luer hub 290, secures onto hub coupling 100. A syringe filled with saline attaches to luer hub 290 and saline is infused through luer hub 290 and into flow directed catheter 50.

[0025] Figure 4 illustrates the flow directed catheter 50 inserted into the vasculature 400. Guiding catheter 30 is located in the vascular territory 400 proximal to the intended embolization site 480. In general the intended embolization site 480 is a region of relatively high flow as associated with an arteriovenous malformation or fistula. Flow directed catheter 50 is extended from the guiding catheter 30 and traverses the vasculature 400 towards the intended embolization site 480. Once the intended embolization site 480 is reached various types of therapeutic agents such as platinum coils, polyvinylalcohol particles, ethanol or cyanoacrylate adhesives may be delivered to treat the lesion. For regions of low flow, flow directed catheter 50 may be used in conjunction with a guidewire inserted in the lumen to access lesions.

Those skilled in the art will appreciate that the flow directed catheter of the present invention may be manufactured from various materials and with various durometers to suit the desires of different physicians.

[0026] Various modification and changes in detail may be made to the above-described embodiments and examples without departing from the spirit and scope of the invention. It is therefore intended that all such matter as described in the foregoing description and shown in the attached drawings be considered as illustrative only and not limiting.

Claims

1. A flow directed catheter comprising a proximal connector hub, a relatively stiff proximal tubular section bonded to the hub, a highly flexible distal tubular section and a relatively short tubular strain relief section interposed between the proximal tubular section and the distal tip section, said tubular strain relief section being more flexible than the proximal tubular section and less flexible than the distal tubular section and being formed of a polymeric material containing a radiopaque agent.

2. The flow directed catheter as defined in Claim 1, wherein the tubular strain relief section is formed of

a polymeric material containing from 40 to 75 weight percent of a radiopaque agent.

3. The flow directed catheter as defined in Claim 1, wherein the tubular strain relief section is thermally fused to the distal end of the proximal tubular section and the distal tubular section is thermally fused to the distal end of the tubular strain relief section.

4. The flow directed catheter as defined in Claim 1, wherein the highly flexible distal section is more than twenty times the length of the strain relief section and the relatively stiff proximal section is more than 10 times the length of the highly flexible distal section.

5. The flow directed catheter as defined in Claim 3, wherein the proximal tubular section has durometer of between 60D and 90D, the strain relief section has a durometer of between 25D and 50D and the distal tubular section has a durometer of between 50A and 90A.

6. The flow directed catheter as defined in Claim 5, wherein the distal tubular section has a length of between 10 and 50 centimeters.

7. The flow directed catheter as defined in Claim 6, wherein the distal tubular section is comprised of a proximal segment and a distal segment and the proximal segment is more flexible than the strain relief section and the distal segment is more flexible than the proximal segment.

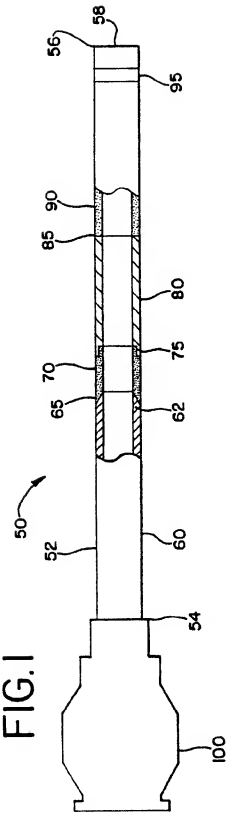


FIG.1

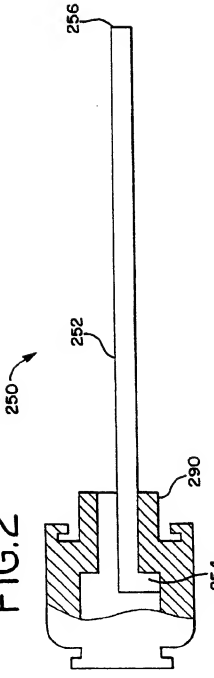


FIG.2

FIG.4

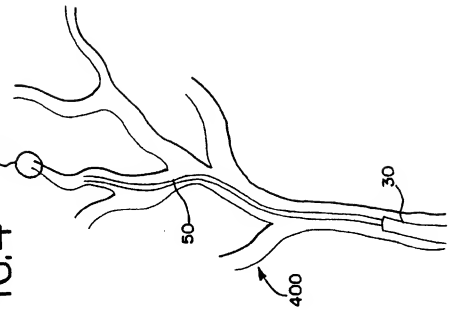
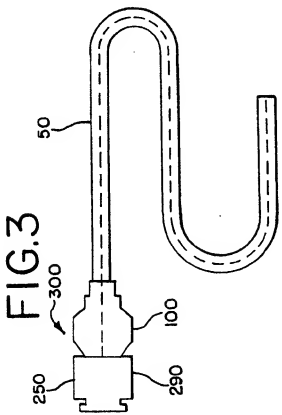


FIG.3



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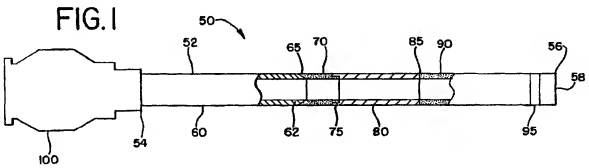
(54) Flow directed catheter having radiopaque strain relief segment

(57) A flow directed catheter for use in medical diagnostic or therapeutic procedures having a strain relief segment between the relatively stiff proximal section of the catheter and the floppy distal tip portion in which the strain relief segment is formed of a polymeric material containing a radiopaque agent.

FIG. 1



EP 0 970 715 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 30 5130

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X Y	WO 97 48435 A (MEDTRONIC, INC.) 24 December 1997 (1997-12-24) * abstract * * page 4, line 18 - page 5, line 24 * * page 7, line 15 - line 17 * * page 9, line 18 - line 30 * * page 10, line 11 - line 26; figures 1-4 * ---	1-6 7	A61M25/00
Y	EP 0 810 003 A (TARGET THERAPEUTICS, INC.) 3 December 1997 (1997-12-03) * abstract * * column 8, line 51 - line 57; figure 1 * ---	7	
X Y	WO 96 40342 A (CARDIMA, INC.) 19 December 1996 (1996-12-19) * abstract * * page 3, line 8 - line 30; claims 1,6-11; figures 1,6-11 * ---	1-6 7	
Y	US 5 658 263 A (DANG ET AL.) 19 August 1997 (1997-08-19) * abstract * * column 3, line 44 - line 61; figures 1,2 * ---	7	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61M
A	US 5 569 218 A (BERG) 29 October 1996 (1996-10-29) ---		
A	US 5 171 232 A (CASTILLO ET AL.) 15 December 1992 (1992-12-15) -----		

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	14 April 2000	Michels, N

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